

REMARKS

STATUS OF THE CLAIMS

Claims 1, 2, 4, 5, 7, 8, 10, 11, 13-18, 21-26, 31, 34, 35 and 38-47 were pending as shown in the Response After Final mailed January 18, 2005, which amendments were entered upon filing of an RCE on March 17, 2005. By virtue of the present amendment, withdrawn claim 1 and examined claim 34 have been amended as shown above to make explicit that the first or second polypeptide comprises a Cys2-His2 zinc finger polypeptide, as described throughout the specification as filed, for example on page 23, lines 4-11. Withdrawn claims 35 and 38 have been amended to correct antecedence. Claims 16-18 have been canceled. Accordingly, claims 1, 2, 4, 5, 7, 8, 10, 11, 13-15, 21-26, 31, 34, 35 and 38-47 are pending and claim 34 is under consideration.

Applicants note that method claims 1, 2, 4, 5, 7, 8, 10, 11, 13-15, 21-24, 31, 35, 38-42, 46 and 47 have all limitations of composition claim 34. Accordingly, upon allowance of claim 34, these method claims should be rejoined.

REJECTIONS WITHDRAWN

Applicants note with appreciation that the rejections of claim 34 under 35 U.S.C. § 102 (e) based on Crabtree, Natesan '653, Natesan '709 and Pomerantz have been withdrawn.

35 U.S.C. § 112, FIRST PARAGRAPH, NEW MATTER

Claim 34 was rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. In particular, it was alleged that there is no description for the recitation that the ligand binds to both the first and second polypeptides of the system (Office Action, pages 4-6).

Because the specification as filed more than adequately describes this recitation, Applicants traverse the rejection and supporting remarks.

It is well settled that the proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. *See, e.g., In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981) and MPEP § 2163.06. The Office Action implies that literal support is required, when, in fact, relevant portions of M.P.E.P. § 2163.02 omitted from the Office Action, specifically indicate the reverse, namely:

The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.

Thus, the written description requirement is satisfied if the specification reasonably conveys possession of the invention to one skilled in the art. *See, e.g., In re Lukach*, 169 USPQ 795, 796 (CCPA 1971). The disclosure must be read in light of the knowledge possessed by the skilled artisan at the time of filing, for example as established by reference to patents and publications available to the public prior to the filing date of the application. *See, e.g., In re Lange*, 209 USPQ 288 (CCPA 1981). Moreover, the burden is on the Examiner to provide evidence as to why a skilled artisan would not have recognized that the applicant was in possession of claimed invention at the time of filing. *Vas Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991); *In re Wertheim*, 191 USPQ 90 (CCPA 1976).

In the pending case, the as-filed specification clearly conveys that Applicant was in possession of methods in which the ligand component binds to both the polypeptide components. References are made throughout the specification to the fact that the ligand may bind to one or more of the components of the system (*see, e.g.,* page 2, lines 8-10; page 10, lines 4-10; page 49, lines 3-4, lines 16-18 and lines 25-28; page 53, line 18, emphasis added):

Ligand mediated association and dissociation of proteins is also known, in which the ability of a protein to interact with another protein is dependent on the **binding of a ligand to one or both proteins**. ...

The term "modulatable by" is used to indicate that the binding of the first molecule to the second molecule can be modulated or affected by the ligand. ... and as applied to a protein switch, the binding of the two polypeptide molecules is modulated or affected by the ligand. In other words, the ligand can modulate, affect, regulate, adjust, alter, or vary the binding of the first molecule to the second molecule.

A ligand according to the invention is typically any molecule capable of **binding to any of the other components** of the switching system. ...

As applied to a protein switch, a ligand is any molecule capable of binding to the polypeptide binding molecule (including a polypeptide binding protein), or another protein.

Ligand mediated protein-protein association is described for example in [citations omitted, including **citations describing ligands that mediate protein-protein dimerization by binding to both proteins**]. ...

...With regard to protein switches, the methods of the present invention typically involve using a tripartite configuration of one or more first polypeptide molecules, one or more ligands and one or more second polypeptides as describes above to screen for (i) polypeptide binding molecules that bind to a (another) target polypeptide in a manner that is modulatable by a ligand and/or (ii) ligands that modulate binding of two polypeptides to each other. ...

Thus, it is more than abundantly clear that the specification fully supports methods in which the ligand binds to both the first and second polypeptides. The Office has not provided any evidence supporting the assertion that the specification does not disclose a ligand binding to both components of a switching system.

Furthermore, the specification does not need to teach that the ligand must bind to both components in all cases. Rather, it is axiomatic that claim amendments can be fairly made (and do not constitute new matter) if the specification reasonably apprises the skilled artisan of the particular embodiment recited by the amendment. Here, embodiments using a ligand that binds to both polypeptide components are described in the specification and, therefore, Applicants are entitled to amend their claims to be directed to these embodiments. By choosing to add this described embodiment to the independent claims, Applicants did not introduce new matter.

In view of these facts and the failure of the Office to provide evidence as to why the skilled artisan would not have understood that Applicant was in possession of the subject matter of the pending claims, Applicants submit that the rejection cannot be maintained. No new matter was added as a result of these amendments and withdrawal of this rejection is respectfully requested.

In any event, the rejection is obviated by the foregoing amendments, which remove the recitation "wherein the ligand binds to both polypeptides."

35 U.C.S. § 102

Examined claim 34 is again rejected under 35 U.S.C. § 102(b) as allegedly anticipated by McEwan as evidenced by Bledsoe. (Office Action, pages 3-4). McEwan is cited as before for disclosing a switching system comprising a glucocorticoid receptor which forms a homodimer upon binding to ligand and is capable of binding to DNA.

Claim 34 is directed to a switching system comprising first and second polypeptides and a ligand, wherein the first polypeptide binds to the second polypeptide in a manner modulatable by a ligand. Both the first and second polypeptides (1) bind to the ligand and (2) bind to DNA. In addition, the first or second polypeptide comprises a Cys2-His2 zinc finger polypeptide.

Accordingly, while Table 1 of McEwan discloses ligand-dependent interaction of glucocorticoid, estrogen and retinoid receptors with other proteins, it is well known (and evidenced by Bledsoe) that homodimers of the glucocorticoid receptor do not comprise Cys2-His2 zinc finger polypeptides as claimed. Thus, withdrawal of this rejection is respectfully requested.

CONCLUSION

Applicant submits that the claims are in condition for allowance and request early notification to that effect. If the Examiner has any further issues or wishes to discuss any of the foregoing, he is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

Date: August 10, 2005

By: _____



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